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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/993,304	11/23/2001	George Jackowski	2132.095	5360

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EXAMINER	
COOK, LISA V	
ART UNIT	**PAPER NUMBER**
1641	

DATE MAILED: 07/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/993,304	JACKOWSKI ET AL.	
	Examiner	Art Unit	
	Lisa V. Cook	1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 April 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 and 39-46* is/are pending in the application.

4a) Of the above claim(s) *39-46* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1 and 39-46* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

HC

S.O.O

DETAILED ACTION

Amendment Entry

1. Applicants response filed March 31, 2005 is acknowledged. In the amendment filed therein, claims 1, 39 and 44-46 were modified. Claims 2-38 have been canceled without prejudice or disclaimer.

Claim Status

2. Claims 39-46 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 10 December 2004.

3. Currently claim 1 is under consideration.

4. Rejections and/or objections of record not reiterated herein have been withdrawn.

OBJECTIONS WITHDRAWN

Information Disclosure Statement

5. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609 A(1) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the Examiner on form PTO-892 or Applicant on form PTO-1449 has cited the references they have not been considered.

6. The information disclosure statements filed 12 March 2003 has been considered as to the merits prior to first action.

Response to Arguments

Applicant contends that the references cited within the specification but not included in the IDS were merely provided for general information and are not deemed pertinent to the patentability of the claimed invention. Accordingly the objection of the IDS is withdrawn.

Oath/Declaration

7. A new oath or declaration is required because the date for Dr. John Marshall (inventor 2) is omitted. The wording of an oath or declaration cannot be amended. If the wording is not correct or if all of the required affirmations have not been made or if it has not been properly subscribed to, a new oath or declaration is required. The new oath or declaration must properly identify the application of which it is to form a part, preferably by application number and filing date in the body of the oath or declaration. See MPEP §§ 602.01 and 602.02.

Response to Arguments

Applicants have submitted a new Oath/Declaration to correct the noted deficiency therein obviating the objection. The objection is withdrawn.

Specification

8. The use of the trademarks has been noted in this application. (.i.e. SEPHAROSE on page 41 lines 11 and 12, TRITON on page 42 line 19, and TRITON on page 43 line 11). They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

Abstract

9. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited.

The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in .deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

10. The instant application includes legal phraseology "said". Appropriate correction is required.

Response to Arguments

Applicants have corrected all the items listed in numbers 8, 9, and 10 above via amendment. Therefore the objections are withdrawn.

REJECTIONS MAINTAINED

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

11. Claim 1 is rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, credible or asserted utility or a well-established utility.

Claim 1 is drawn to a biopolymer marker consisting of SEQ ID NO:3. While the specification asserts that SEQ ID NO:3 has utility as a diagnostic marker for Alzheimer's disease. The specification also teaches that the biopolymer marker is useful in methods determining the absence, presence, or regulation of SEQ ID NO:3, wherein the difference from control samples indicates that the subject has Alzheimer's disease. These diagnostic methods include for example biopolymer evidencing, characterization, regulation, risk-assessment, and therapeutic identification. The specification also contemplates the use of these methods for diagnosing, staging, monitoring, prognosticating or determining predisposition to Alzheimer's disease.

Applicant also sets forth figures/drawings as evidence of SEQ ID NO:3 as a marker for Alzheimer's disease. However, the figures do not identify SEQ ID NO:3 (which band corresponds to sequence identification number 3) thus a correlation to Alzheimer's is impossible. in two ADH samples (005 and 006) but absent in normal patients as well as other Alzheimer's

No clear difference in up and down regulation of the marker can be determined. The correlation with respect to Alzheimer's disease is also not evident.

Therefore, SEQ ID NO:3 does not appear to be a marker for Alzheimer's disease (clearly distinguishing the disease from control or normal patients).

There are no disclosure or working examples that demonstrate the specifically asserted utility and evidences a substantial utility was well established at the time of filing.

The specification does not enable one of ordinary skill in the art to definitively assess the incidence of the disease in a single test sample. Furthermore, Applicants have not provided any disclosure enabling the use of the biopolymer marker with regard to regulating the presence or absence of said sequence. The disclosure is equally lacking any teaching for how the identified sequence will be utilized to identify therapeutic avenues and regulate a disease state. Accordingly, the specification does not identify a specific, substantial, credible or asserted utility or a well-established utility for SEQ ID NO:3.

There is no disclosure designating how the sequence bound in these methods could be regarded as enabling one of ordinary skill in the art to use SEQ ID NO:3 as a diagnostic marker.

Applicants have not set forth any supporting evidence that suggests that SEQ ID NO:3 is a unique molecular markers for Alzheimer's disease. Based on the analysis set forth above the specification does not exemplify sufficient findings that constitute a specific, substantial or credible utility.

Claim 1 is also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by a specific, substantial or credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Response to Arguments

Applicant argues that claim 1 has both a specific and a well-established utility because the specification discloses that sequences consisting of SEQ ID NO:3 is measurable in patients with Alzheimer's disease but is undetectable or regulated differently in normal patients. This argument was carefully considered but not found persuasive because the disclosure does not clearly correlate sequences consisting of SEQ ID NO:3 with a link to Alzheimer's disease.

First, although the instant specification discloses that SEQ ID NO:3 is related to Alzheimer's disease on pages 46 and 47 (specific utility), the asserted specific utility is not credible because figures 1, 3, and 6 do not exemplify SEQ ID NO:3 as measurable in patients with Alzheimer's disease or undetectable and regulated differently in normal patients.

Specifically, in figure 1, Applicant contends that Band 4 represents SEQ ID NO:3. However, Band 4 is identified in figure 1 as containing the CENP-E protein and 3 unknown proteins. Therefore the appearance of Band 4 may be attributed to either of the 4 proteins therein and it is not clear how Band 4 is unique to only sequences consisting of SEQ ID NO:3. Figure 1 also, identifies four samples from Alzheimer's patients (ADH-004, ADH-005, ADH-006, ADH-008) wherein ADH-004 and ADH-005 appear not to express Band 4 but ADH-006 and ADH-008 appear to differently express Band 4. This is a contradiction to applicant's argument because Band 4 is undetectable in Alzheimer's patient samples ADH-004 and ADH-005.

Band 4 is exemplified in figure 3 as containing the CENP-E protein and 3 unknown proteins. Therefore the appearance of Band 4 may be attributed to either of the 4 proteins therein and it is not clear how Band 4 is unique to only sequences consisting of SEQ ID NO:3.

Figure 3 also, identifies four samples from Alzheimer's patients (ADH-004, ADH-005, ADH-006, ADH-008), one pooled normal human serum sample (Pooled NHS), and four aged matched control samples (ADC(H)-002, ADC(H)-003, ADC(H)-004, ADC(H)-005) wherein Band 4 only appears to be detectable in ADC(H)-002. This is a contradiction to applicant's arguments because Band 4 is *not* measurable in patients with Alzheimer's disease or is it clearly *regulated differently* in normal patients.

In figure 6, Band 4 is only seen in patient sample AG-AD-H-004 while all the other samples do not contain Band 4. This is a contradiction to applicant's arguments because Band 4 is *not* measurable in patients with Alzheimer's disease or is it clearly *regulated differently* in normal patients.

Applicant also contends that the use of SEQ ID NO:3 is well established because a correlation between the claimed peptide (SEQ ID NO:3) and Alzheimer's disease is evident. This argument appears to be based on immunoglobulin (antibody) light chain proteins involved in amyloidosis (Stevens-reference 3 and Lukiw et al.-reference 4) and because SEQ ID NO:3 is a fragment of the immunoglobulin kappa light chain. However, Stevens merely show an association of kappa light chains in amyloidosis and Lukiw et al. only discuss neuroinflammatory signaling in Alzheimer's disease. No direct link between the immunoglobulin kappa light chain or sequences consisting of SEQ ID NO:3 is taught in either reference.

Further, the prior art teaches that Alzheimer's disease has no known cure, no known cause or mechanism, and cannot be definitively assigned as a differential diagnosis in the absence of a post mortem examination. See Patel (Journal of Geriatric Psychiatry and Neurology, Vol.8, 81-95, 1995).

Therefore it would be reasonable to conclude that the utility would not be credible or well established based on the evidence of record. The rejection is maintained.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

12. Claim 1 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claims contain subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation.

Factors to be considered in determining, whether a disclosure would require undue experimentation include 1) the nature of the invention, 2) the state of the prior art, 3) the predictability or lack thereof in the art, 4) the amount of direction or guidance present, 5) the presence or absence of working examples, 6) the quantity of experimentation necessary, 7) the relative skill of those in the art, and 8) the breadth of the claims.

Claim 1 is directed to a biopolymer consisting of SEQ ID NO:3 indicative of Alzheimer's disease. However, the specification does not support this assertion. The specification (in particular page 46) and figures do not definitively correlate the claimed marker consisting of SEQ ID NO:3 to Alzheimer's disease.

Specifically, the specification recites that biopolymers consisting of SEQ ID NO:3 were found or regulated differently in the serum of patients suffering from Alzheimer's disease on page 46, but the specification does not contain any data supporting this contention and the figures do not identify SEQ ID NO:3 as a definitive marker for Alzheimer's. Therefore it is unclear how SEQ ID NO:3 was identified as "notable sequences" or how they were deemed "evidentiary" of a disease state.

There is nothing in the disclosure that would enable one to choose SEQ ID NO:3 as notable sequences among an infinite number of possible proteins or peptides present in a patient sample. There is no correlation between the procedure for screening samples from patients suspected of having a variety of different disease, the presence/absence of SEQ ID NO:3, and the determination, prediction, assessment of Alzheimer's disease.

Furthermore, Applicants have not provided any disclosure enabling the use of the biopolymer marker with regard to regulating the presence or absence of said sequence. The disclosure is equally lacking any teaching for how the identified sequence will be utilized to identify therapeutic avenues and regulate a disease state. There is no disclosure designating how the sequence could be utilized therein, enabling one of ordinary skill in the art to use the sequences in the diagnostic method.

Applicants have not set forth any supporting evidence that suggests that any of the sequences (In particular SEQ ID NO:3) are unique molecular markers for Alzheimer's disease or any other disease and the prior art teaches that disease markers are highly unpredictable and require extensive experimentation.

Hampel et al. (Journal of Neural Transmission, 2004, 11:247-272) disclose the difficulty involved in the discovery of marker candidates for Alzheimer's. In this review, several critical criteria must be meet when determining a marker for Alzheimer's.

These include indication of disease progression, heterogeneity of the clinical population, as well as feasibility of testing. Also of concern are assay sensitivity, frequency of assessments, stability, standardization, dynamic range, and comparative analysis. See page 247-248 Summary.

Further, Tockman et al. (Cancer Research 52:2711s-2718s, 1992) teach considerations necessary for a suspected cancer biomarker (intermediate end point marker) to have efficacy and success in a clinical application. Although the reference is drawn to biomarkers for early lung cancer detection, the basic principles taught are clearly applicable to other disorders.

Tockman teaches that prior to the successful application of newly described markers, research must validate the markers against acknowledged disease end points, establish quantitative criteria for marker presence/absence and confirm marker predictive value in prospective population trials, see abstract. Early stage markers of carcinogenesis have clear biological plausibility as markers of preclinical cancer and **if validated** (emphasis added) can be used for population screening (p. 2713s, column 1).

The reference further teaches that once selected, the sensitivity and specificity of the biomarker must be validated to a known (histology/cytology-confirmed) cancer outcome. The essential element of the validation of an early detection marker is the ability to test the marker on clinical material obtained from subjects monitored in advance of clinical cancer and *link* those marker results with subsequent histological confirmation of disease.

"This irrefutable link between antecedent marker and subsequent acknowledged disease is the essence of a valid intermediate end point [marker]", see page 2714s, column 1, Biomarker Validation against Acknowledged Disease End Points section. Clearly, prior to the successful application of newly described markers, markers must be validated against acknowledged disease end points and the marker predictive value must be confirmed in prospective population trials, see page 2716s, column 2, Summary section.

Tockman reiterates that the predictability of the art in regards to cancer prognosis and the estimation of life expectancies within a population with a disease or disorder are highly speculative and unpredictable.

The instant disclosure has not addressed the issues taught in the prior art as crucial to the discovery of a biopolymer marker.

The nature of the invention- the invention is directed to disease markers or biopolymers.

The state of the prior art- the prior art of record fails to disclose the particular biopolymers in any disease state.

The predictability or lack thereof in the art- there is no predictability based on the instant specification that the biopolymers are indicative of any disease state including Alzheimer's disease.

The amount of direction or guidance present- appropriate guidance is not provided by the specification for the claimed biopolymers.

The presence or absence of working examples- working examples are not provided in the specification that exemplify the biopolymers as markers for any disease.

The quantity of experimentation necessary- it would require undue amount of experimentation for the skilled artisan to make and use the biopolymers as claimed.

*The relative skill of those in the art-*the level of skill in the art is high.

The breadth of the claims- as recited, the instant claims are directed to biopolymers consisting of SEQ ID NO:3 being indicative of Alzheimer's disease state.

While it is not necessary to show working examples for every possible embodiment, there should be sufficient teachings in the specification that would suggest to the skilled artisan that the breadth of the claimed biopolymer is enabled. This is not the case in the instant specification.

In view of the teachings of In re Wands, 8 USPQ2d 1400, it has been determined that the level of experimentation required to enable the breadth of the claims is undue.

Therefore, in view of the insufficient guidance in the specification, extensive experimentation would be required to enable the claims and to practice the invention as claimed.

Response to Arguments

Applicant argues that the evidence of enablement need not be conclusive but merely convincing to one of skill in the art and the instant specification provides sufficient evidence to convince one of skill in the art that the claimed peptide (SEQ ID NO:3) is linked and/or associated with Alzheimer's disease.

This argument was carefully considered but not found persuasive because the specification must teach how to make and use the invention, not teach how to figure out for oneself how to make and use the invention. In re Gardner, 166 USPQ 138 (CCPA 1970).

Although the instant specification discloses that SEQ ID NO:3 is related to Alzheimer's disease on pages 46 and 47, figures 1, 3, and 6 do not exemplify SEQ ID NO:3 as measurable in patients with Alzheimer's disease or undetectable and regulated differently in normal patients.

Specifically, in figure 1, Applicant contends that Band 4 represents SEQ ID NO:3. However, Band 4 is identified in figure 1 as containing the CENP-E protein and 3 unknown proteins. Therefore the appearance of Band 4 may be attributed to either of the 4 proteins therein and it is not clear how Band 4 is unique to only sequences consisting of SEQ ID NO:3. Figure 1 also, identifies four samples from Alzheimer's patients (ADH-004, ADH-005, ADH-006, ADH-008) wherein ADH-004 and ADH-005 appear not to express Band 4 but ADH-006 and ADH-008 appear to differently express Band 4. This is a contradiction to applicant's argument because Band 4 is undetectable in Alzheimer's patient samples ADH-004 and ADH-005.

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This is a contradiction to applicant's arguments because Band 4 is *not* measurable in patients with Alzheimer's disease or is it clearly *regulated differently* in normal patients.

In figure 6, Band 4 is only seen in patient sample AG-AD-H-004 while all the other samples do not contain Band 4. This is a contradiction to applicant's arguments because Band 4 is *not* measurable in patients with Alzheimer's disease or is it clearly *regulated differently* in normal patients.

Applicant also contends that the use of SEQ ID NO:3 in Alzheimer's disease is evident. This argument appears to be based on immunoglobulin (antibody) light chain proteins involved in amyloidosis (Stevens-reference 3 and Lukiw et al.-reference 4) and because SEQ ID NO:3 is a fragment of the immunoglobulin kappa light chain. However, Stevens merely show an association of kappa light chains in amyloidosis and Lukiw et al. only discuss neuroinflammatory signaling in Alzheimer's disease. No direct link between the immunoglobulin kappa light chain or sequences consisting of SEQ ID NO:3 is taught in either reference.

Further, the prior art teaches that Alzheimer's disease has no known cure, no known cause or mechanism, and cannot be definitively assigned as a differential diagnosis in the absence of a post mortem examination. See Patel (Journal of Geriatric Psychiatry and Neurology, Vol.8, 81-95, 1995).

The prior art also teaches that immunoglobulin kappa light chains can be linked to infectious disease and autoimmune diseases like Sjogren's syndrome. See Downie-Doyle (Genes and Immunity, October 2002, Vol.3, No. Supplement 1, pp.S63-S65-Abstract Only). Accordingly the claimed immunoglobulin kappa light chains and its fragments could be possibly linked to diseases other than Alzheimer's and one of skilled in the art would require undue experimentation to distinguish between the particular diseases.

The enablement issue is whether one skilled in the art could have made or used the sequence consisting of SEQ ID NO:3 as a link or in association with Alzheimer's disease without undue experiment at the time the application was filed. The specification and the prior art have not clearly set forth a link between the claimed sequence and Alzheimer's, therefore the rejection is maintained.

13. For reasons aforementioned, no claims are allowed.

14. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

15. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (571) 273-8300, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to Group TC 1600 whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see httpr//pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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